DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 3, 2015

Lanterna Medical Technologies
% Rich Jansen, Pharm.D.
Silver Pine Consulting, LLC
11821 Bramble Cove Drive
Fort Myers, Florida 33905

Re: K150507
Trade/Device Name: Santis™ Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH
Dated: March 23, 2015
Received: March 24, 2015

Dear Dr. Jansen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150507

Device Name
Santis Pedicle Screw System

Indications for Use *(Describe)*
The Santis Pedicle Screw System is intended for immobilization and stabilization of the spine. The Santis Pedicle Screw System is indicated for posterior, noncervical pedicle fixation as an adjunct to fusion in skeletally mature patients using autograft and/or allograft for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Date Prepared: March 10, 2015
Submitter Lanterna Medical Technologies
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Regulatory Contact: Rich Jansen, Pharm. D.
Silver Pine Consulting
richj@s-pineconsulting.com

Device: Santis™ Pedicle Screw System

Product Class:	Class III
Classification:	21 CFR §888.3070 Pedicle Screw Spinal System
Common Name:	Pedicle Screw System
Product Codes:	NKB, MNI, MNH
Panel Code:	87

Purpose: The purpose of this submission is to gain clearance of previously cleared devices as sterile, packaged products.

Predicate Device(s): The primary predicate device is the Santis™ Pedicle Screw System (K133063)

Device Description:
The Santis™ Pedicle Screw System is comprised of: straight and pre-curved rods, pedicle screw assemblies with both cannulated and non-cannulated screws, compression retaining assemblies, cross connectors and a set screw. Various forms and sizes of these implants are available so that adaptations can be utilized to take into account the unique pathology of individual patients. The Santis™ Pedicle Screw System can be implanted either by an open procedure or percutaneous MIS approach, or a combination of both during the same procedure.
Components are made of Ti6Al4V ELI, a titanium based alloy, which complies with ASTM F136, or cobalt chrome per ASTM F1537.

Indications for Use:

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Technological Characteristics:

The technological characteristics of the subject device and the predicate device are summarized below.

	Subject Device
Indications for Use	Same as predicate
Surgical Technique	Same as predicate
Screw Options and sizes	Same as predicate
Cross Connectors	Same as predicate
Rod sizes	Same as predicate
Materials	Same as predicate

Performance Standards:

Performance testing includes:

Validation	**Standard**	**Pass/Fail**
Package integrity	F1886-09, F1929-12, D3078 and F2096	Passed
Gamma sterilization	ANSI/AAMI/ISO 11137 and 11607	Passed
Shelf life	ASTM F1980	Passed
Shipping validation	ASTM D4169	Passed

Conclusion:

Lanterna Medical Technologies concludes that the Santis™ Pedicle Screw System is substantially equivalent to the previously cleared Santis™ Pedicle Screw System. The packaging and sterilization processes have been validated and raise no new questions of safety or effectiveness.